PCT/AU03/01677

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I, JONNE YABSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003900176 for a patent by ROFIN AUSTRALIA PTY LTD as filed on 16 January 2003.

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JONNE YABSLEY
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AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

Applicant(s):

ROFIN AUSTRALIA PTY LTD

Invention Title:

PHOTODYNAMIC THERAPY LIGHT SOURCE

The invention is described in the following statement:

PHOTODYNAMIC THERAPY LIGHT SOURCE

FIELD OF THE INVENTION

This invention relates to a photodynamic therapy light source for treating skin conditions of a patient.

BACKGROUND ART

Photodynamic therapy basically comprises the application of light of a particular wavelength to a patient's skin in order to repair damage, destroy unwanted cells or to provide information enabling diagnosis of various skin conditions.

Conventional light sources which are used in photodynamic therapy are not particularly flexible and generally are used to address only a single radiation bandwidth. The conventional systems also do not provide any feedback in relation to the treatment process or progress made by a patient, thereby increasing the difficulty of providing records of treatment and also of the success or progress of a treatment strategy.

In one specific prior art form of treatment, poforins, which are a breakdown component of red blood cells, were administered to a patient in order to attempt to identify surface cancer cells. Poforins have strong absorption of orange-red light and by injecting a patient with poforins, cancer cells could possibly be identified because the cancer cells would take up the poforins, thereby producing strong absorption to the red-orange light. Thus, by applying light of that colour to the person's skin, poforins which have been taken up can be identified and therefore the location of cancer cells could possibly be identified. This procedure had the disadvantage that the poforins were injected into a patient and therefore, the entire patient's body was subjected to the poforins.

In more recent times, chemicals have been used in order to cause localised creation of poforins. Typically,

one chemical which has been used is ALA (alanim laevulenin acid). This procedure typically requires the chemical to be applied to the area to be treated by applying the chemical only to that area. Typically, the chemical is applied some 8-20 hours before treatment. Light of the prescribed wavelength, such as from 580 to 680 nm is used to illuminate the treated area. This wavelength does not damage blood cells because blood cells reflect light in this wavelength band.

Another chemical which has been used in more recent times is methyl ester of ALA. This chemical takes up more quickly than ALA, and typically in 3-5 hours, thereby reducing the time period between the application of the chemical and the treatment.

Other chemicals are currently being developed which can be used in conjunction with photodynamic therapy in order to treat a patient.

SUMMARY OF THE INVENTION

The object of the invention is to provide a photodynamic therapy light source which addresses at least one of the problems of the prior art sources.

It should be understood that in this specification, the words "light" and "light source" are not limited to the visible part of the electromagnetic spectrum and includes parts of the electromagnetic spectrum outside the visible range of wavelengths.

The invention, in a first aspect, may be said to reside in a photodynamic therapy light source including:

a light source for producing illumination;

filter means having a plurality of filter elements for filtering the illumination produced by the light source to provide illumination in a specific bandwidth; and

control means for receiving data from a database of patient information and for controlling the photodynamic therapy light source so as to provide a dose

of illumination at a specific wavelength bandwidth and for a predetermined time period.

This aspect of the invention therefore enables more than one bandwidth to be selected and for an appropriate bandwidth to be selected having regard to the patient and the nature of the treatment which may be required. The invention also enables the light source to control the application of the light within that bandwidth for a predetermined time so that a certain dose is provided dependant on patient information stored in a database.

Preferably, the filter means comprises a first filter wheel having at least a filter element for transmitting ultraviolet light, a filter element for transmitting infrared light, and a filter element for transmitting light in the visible spectrum, and a blank region for preventing transmission of any light from the light source, and a second filter wheel having a plurality of filter elements for selecting a particular bandwidth of wavelength for transmission through the second filter wheel.

Preferably, the first and second filter wheels include drive means for rotating the filter wheel so as to bring a selected one of the filter elements into alignment with the light source so that light of the required wavelength is provided.

Preferably, the photodynamic therapy light source includes a light guide for receiving the light from the filter means and for conveying the light to a patient.

Preferably, the photodynamic therapy light source includes a camera for providing an image of a region of the patient which is to be treated.

Preferably, the camera is a charged couple device array and light is transmitted to the camera by an image fibre.

Preferably, the image fibre is included in the light guide.

Preferably, the photodynamic therapy light source includes a spectrum analyser for analysing the spectrum of reflected radiation from a region of the patient to be treated.

Preferably, the spectrum analyser receives light reflected from the region of the patient via a fibre waveguide.

Preferably, the fibre waveguide is included in the light guide.

Preferably, the second filter wheel includes a tilt mechanism for tilting the filter wheel to shift the bandwidth provided by each of the filter elements of the second filter wheel.

Preferably, the photodynamic therapy light source also includes a light intensity unit for measuring the intensity of light provided to the patient from the filter means and for determining the dose applied to the patient based on the intensity of the light, and also the distance the light guide will be held away from the patient during treatment of the patient.

Preferably, the control means is connectable to an external computer for storing the database and for enabling user input of commands and data.

The invention in a second aspect may be said to reside in a photodynamic therapy light source including:

a light source for producing illumination;

a light guide for conveying light to a patient for treating the patient; and

a camera for receiving light reflected from the treatment area of the patient, so as to obtain an image of the treatment area to provide a visual indication of the progress of treatment.

Thus, according to this aspect of the invention, a photograph of the treated area of the patient can be captured each time the patient is treated to obtain a record of the manner in which treatment is progressing. The photographs also enable assessment of progress to be

made immediately after each treatment by comparing the photograph obtained after the last treatment with an image of the treatment immediately following a subsequent treatment. This information can be stored to provide a permanent record of the treatment progress.

Preferably, the photodynamic therapy light source includes filter means having a plurality of filter elements for filtering the illumination provided by the light source to provide illumination in a specific wavelength bandwidth.

Preferably, the photodynamic therapy light source includes control means for receiving data from a database of patient information and for controlling the photodynamic therapy light source to provide a treatment dose based on the said information.

Preferably, the filter means comprises a first filter wheel having at least a filter element for transmitting ultraviolet light, a filter element for transmitting infrared light, and a filter element for transmitting light in the visible spectrum, and a blank region for preventing transmission of any light from the light source, and a second filter wheel having a plurality of filter elements for selecting a particular bandwidth of wavelength for transmission through the second filter wheel.

Preferably, the first and second filter wheels include drive means for rotating the filter wheel so as to bring a selected one of the filter elements into alignment with the light source so that light of the required wavelength is provided.

Preferably, the light source includes a light guide for receiving the light from the filter means and for conveying the light to a patient.

Preferably, the camera is a charged couple device array and light is transmitted to the camera by an image fibre.

Preferably, the image fibre is included in the

light guide.

Preferably, the photodynamic therapy light source includes a spectrum analyser for analysing the spectrum of reflected radiation from a region of the patient to be treated.

Preferably, the spectrum analyser receives light reflected from the region of the patient via a fibre waveguide.

Preferably, the fibre waveguide is included in the light guide.

Preferably, the second filter wheel includes a tilt mechanism for tilting the filter wheel to shift the bandwidth provided by each of the filter elements of the second filter wheel.

Preferably, the photodynamic therapy light source also includes a light intensity unit for measuring the intensity of light provided to the patient from the filter means and for determining the dose applied to the patient based on the intensity of the light, and also the distance the light guide will be held away from the patient during treatment of the patient.

Preferably, the control means is connectable to an external computer for storing the database and for enabling user input of commands and data.

The invention, in a further aspect, may be said to reside in a photodynamic therapy light source including:

a light source for providing illumination;

a light guide for conveying the illumination to a region of a patient to be treated; and

a spectrum analyser for receiving reflected light from the patient and for providing a spectrum of that light so as to provide an indication of the nature of treatment required, or the manner in which treatment is progressing.

Preferably, the photodynamic therapy light source includes filter means having a plurality of filter

elements for filtering the illumination provided by the light source to provide illumination in a specific wavelength bandwidth.

Preferably, the photodynamic therapy light source includes control means for receiving data from a database of patient information and for controlling the photodynamic therapy light source to provide a treatment dose based on the said information.

Preferably, the filter means comprises a first filter wheel having at least a filter element for transmitting ultraviolet light, a filter element for transmitting infrared light, and a filter element for transmitting light in the visible spectrum, and a blank region for preventing transmission of any light from the light source, and a second filter wheel having a plurality of filter elements for selecting a particular bandwidth of wavelength for transmission through the second filter wheel.

Preferably, the first and second filter wheels include drive means for rotating the filter wheel so as to bring a selected one of the filter elements into alignment with the light source so that light of the required wavelength is provided.

Preferably, the light source includes a light guide for receiving the light from the filter means and for conveying the light to a patient.

Preferably, the photodynamic therapy light source includes a camera for providing an image of a region of the patient which is to be treated.

Preferably, the camera is a charged couple device array and light is transmitted to the camera by an image fibre.

Preferably, the image fibre is included in the light guide.

Preferably, the spectrum analyser receives light reflected from the region of the patient via a fibre waveguide.

Preferably, the fibre waveguide is included in the light guide.

Preferably, the second filter wheel includes a tilt mechanism for tilting the filter wheel to shift the bandwidth provided by each of the filter elements of the second filter wheel.

Preferably, the photodynamic therapy light source also includes a light intensity unit for measuring the intensity of light provided to the patient from the filter means and for determining the dose applied to the patient based on the intensity of the light, and also the distance the light guide will be held away from the patient during treatment of the patient.

Preferably, the control means is connectable to an external computer for storing the database and for enabling user input of commands and data.

BRIEF DESCRIPTION OF THE DRAWINGS

A preferred embodiment of the invention will be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a schematic layout drawing of a photodynamic therapy light source according to the preferred embodiment;

Figure 2 is a block diagram of the main control system according to the preferred embodiment; and

Figure 3 is a flow chart illustrating operation of the device according to the preferred embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to Figure 1, the photodynamic therapy light source is shown in schematic form. The photodynamic therapy light source includes a light source 10 for providing illumination. The light source may be a lamp of any suitable design for providing illumination across a relatively wide bandwidth, including at least the

UV spectrum, visible light spectrum and the infrared spectrum.

A primary filter wheel 12 is provided which has four filter elements 14, 16, 18 and 20. The filter element 14 is in the form of a mirror which effectively reflects UV radiation but allows white light or light in the visible spectrum to pass, the element 16 removes the visible part of the spectrum and enables ultraviolet light to pass, the filter element 18 allows the visible spectrum to pass, and the element 20 is effectively a blank, which prevents any radiation from the light source 10 from passing through the filter wheel 12. The filter wheel 12 has a drive motor 22 for rotating the filter wheel 12 to a required one of the filter elements 14, 16, 18 or 20 into alignment with the light source 10 so that radiation from the light source 10 can pass through the selected one of the filter elements 14 to 18 or be blocked by the element 20. A second filter wheel 24 is provided which has a plurality of filter elements 24′. In the preferred embodiment, 12 such elements are provided. Each of the elements forms a filter for passing a specific wavelength band. If desired, at least one of the elements 24′ can simply be completely open, so as to enable the light as filtered by the first filter wheel 12 to pass without any additional filtering. In the preferred embodiment, the filter elements 24′ are intended to filter the light across the visible part of the electromagnetic radiation spectrum to provide discrete bandwidths from, for example, 400 to 700nm. Thus, the first element may allow light from 400 to 450nm to be transmitted, the second 450 to 500nm, and so on.

The filter wheel 24 has a drive motor 26 for rotating the filter wheel to bring a selected one of the elements 24′ into alignment with the light source 10.

The filter wheel 24 also has a tilt motor 28 for slightly tilting the wheel 24. Tilting the wheel 24 will cause the bandwidth of light transmitted by each of the

filter elements 24′ to be slightly shifted upwardly by a certain amount to thereby fine tune the bandwidth which is passed by each of the filter elements 24′. For example, if an element 24′ is selected which gives a bandwidth of 580 to 670 nm about a centre wavelength of 625 nm, tilting of the filter wheel 24 can tune that band downwardly by up to about 30 nm so that the band becomes 550 to 640 nm. The amount of tilt will determine the amount of adjustment of the bandwidth, and therefore, fine tuning of the bandwidth which is passed by the filter 24 can take place by tilting the mirror by means of the tilt means motor 28.

Both of the wheels 12 and 24 have a detector in the form of a Hall effect device (not shown) so the position of the wheels 12 and 24 can be determined and the wheels homed to ensure accurate movement of the wheels so the appropriate one of the filter elements of each of the wheels is moved into alignment with the light source 10 as is required.

The motors 22, 26 and 28 are controlled by a control board and interface device 40 which will be described in more detail with reference to Figure 2. The device 40 is coupled to an external computer system 50, such as a PC or the like. It should be understood that the computer system 50 is generally separate from the photodynamic therapy light source, and may be the practitioner's personal computer into which appropriate software is loaded, or a special computer merely to function with the photodynamic therapy light source of the preferred embodiment. However, in other embodiments, the computer system 50 could be incorporated into the photodynamic therapy light source if required.

A power supply 55 is provided for providing power to the device 40 and also to the light source 10. A remote handheld device 56 may also be connected to device 40 for remote operation of the device 40 or, alternatively, input commands can be input by way of the computer 50.

Light which passes through the filter wheels 12 and 24 is received by a light guide 60 in the form of a flexible tube. The light guide 60 may be made in accordance with International patent application number PCT/US99/18228, the contents of which are incorporated into this specification. However, the light guide 60 may be in the form of a bundle of optical fibres for conveying light from the filter wheel 24 to light output end 62 which can be located adjacent a patient's skin for illuminating the patient's skin with light.

In the preferred embodiment of the invention, a camera 70 is provided which is in the form of a charge couple device for capturing an image of the treatment area of a patient. The camera 70 is provided with an optical fibre 72 which passes from the camera 70, through the light guide 60 to outlet end 74. Thus, light which reflects from the treatment area of the patient will travel along the fibre 72 from the end 74 to the camera 70. A filter wheel 76 may be located in the path of light leaving the fibre 72 and before the light is detected by the camera 70, for filtering the light to a specific bandwidth of interest in which it is desired to be captured by the camera for storage purposes.

The camera is coupled to the computer 50 so that images captured by the camera 70 can be stored in the computer 50.

A spectrum analyser 80 is also provided in the photodynamic therapy light source for analysing the spectrum of light reflected from the treatment area of the patient. The analyser 80 is coupled with an optical fibre 82 which has an end 84 at the outlet end 62 of the waveguide 60. Light reflected from the patient also passes into the fibre 84 and is received by the analyser 80 so that the analyser 80 can analyse a spectrum of light to determine its characteristics, and therefore to determine or guide the treatment program.

The analyser 80 is also connected to the camera

50 so that the data obtained by the analyser 80 can be stored in the computer 50 while used by the computer 50 for analysis purposes to determine the nature of a treatment strategy.

A detector unit 90 for determining the intensity of light provided from the filter wheel 24, and therefore the nature of the dose which is required, is also provided within the photodynamic therapy light source. The unit 90 includes an optical fibre 92, which has an inlet end 93 which is arranged within the beam of light which passes from the filter wheel 24 so that the intensity of that light can be monitored by the unit 90. The dose of light which is applied to a patient will depend on the intensity of the light which is provided through the wheel 24, and also the distance the end of the waveguide 62 is from the treatment area of the patient. The unit 90 is connected to computer 50 and a lookup table of intensity values and distant values can be retained in the computer 50 or in the unit 90, and which can be used to determine the timing of application of the light to provide the required dose according to the treatment protocols. For example, if a dose of 20 joules is required, and it is determined that the light intensity is X and the distance the end 62 will be held from the treatment area of the patient is Y, a lookup table will provide the time period which will be needed in order to provide that 20 joule dose for the parameters X and Y. Thus, the start of the treatment can be determined, and the end of the treatment determined after the time period expires, by rotating the wheel 12 so as to bring the element 20 into alignment with the light source 10 which will shut off the supply of light from the light source 10.

Figure 2 shows a block diagram of the main control section of the preferred embodiment. The main control section includes a controller 100 which is shown in dotted lines, and which is generally included within the photodynamic therapy light source, and an external

computer 50 which couples to a database, or includes a database 52, which includes patient information and treatment protocols.

The computer 50 couples to control device 40 which in turn controls the motors 22, 26 and 28 previously mentioned. The motor position sensors, namely the Hall effect device previously mentioned, which are schematically shown by reference 102 in Figure 2, provide data to the device 40 to determine the position of the filter wheels to ensure that the correct filter element is brought into alignment with the light source 10. A timer 104 is also provided for timing the dose as determined by the dose unit 90 and the computer 50. After the time period has expired, the timer 104 will provide a signal to the controller 40 which in turn will rotate the filter wheel 22 to bring the blocking element 20 of the filter wheel 12 into registry of the light source to thereby shut off the supply of light source to the patient. A light output power monitor 106 is also provided for measuring the light output of the light source 10. An on/off power supply 55 couples to a pulse width modulator control 107 for controlling the light output power monitor 106, the timer 104 and the motor position sensors 102. The on/off power supply 55 also supplies power to the light source 10.

With reference to Figure 3, a flow chart of the operation of the photodynamic therapy light source according to the preferred embodiment is shown.

Prior to any treatment with the light source, the patient is first treated with a chemical which is applied by rubbing the chemical into the patient's skin. Typically, the area is then covered and a predetermined time is allowed to elapse to enable the chemical to be taken up by the patient's skin. After the predetermined time period expires, the patient then presents for treatment or diagnosis.

With reference to the flow chart of Figure 3, at

step 1, the computer 50 is turned on, as is the power supply 55. At step 2, the camera 70 is switched on, and at step 3, data relating to the particular patient in question is sourced from the computer 50 and the database 52. At step 4, a spectra of the area treatment of the patient is taken by means of the spectrum analyser 80. This step enables the natural response of the patient's skin to light to be determined. For example, if the patient has particularly dark skin, light of a particular wavelength will be absorbed or reflected which may be different to the case where a patient has particularly light skin. This enables the practitioner to determine wavelengths which would be most suitable to treat the skin type belonging to the patient in accordance with the type of chemical which has been applied or, alternatively, to select both a wavelength and chemical which will be useful for treating the condition required by the patient. At step 5, the light source 10 is switched on and the filter wheel 12 is controlled so that the element 20 is in position with the light source 10 so no light is as yet transmitted to the patient. The timer 104 is set to zero.

At step 6, the filter wheel 12 is controlled so that ultraviolet light is able to pass through the filter wheel 12 and through the wheel 24, and at step 7, the area of the patient is viewed for fluorescence, which is caused by the application of the particular chemical to the user's skin and the application of light in step 6.

The area which is fluorescing, which identifies the area which requires treatment, is marked for treatment in step 8.

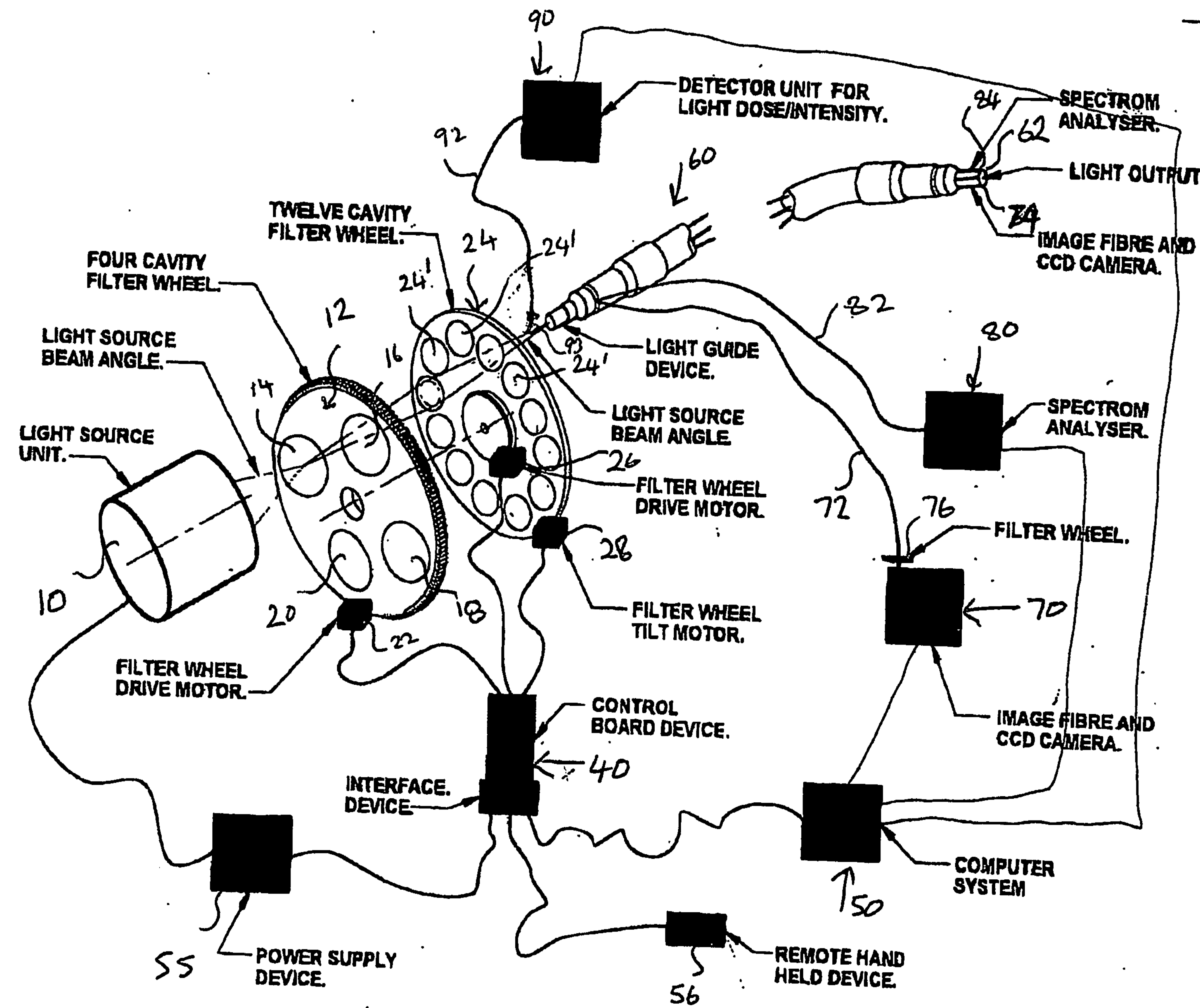
At step 9, the dose required is calculated depending on the nature of treatment the patient is undergoing, and the information relating to the patient which is stored in the database 52, and also based on the intensity of the light measured by the unit 90 and the distance the end 62 will be held away from the patient. At step 10, the treatment wavelength is selected and the

wheel 24 is controlled to bring one of the elements 24' into alignment with the light source 10. Simultaneously, the wheel 12 is also rotated to bring one of the elements into alignment with the light source 10 so as to produce the required bandwidth from the filter 24. If necessary, the wheel 24 can be tilted by the tilt motor 28 to fine tune the wavelength bandwidth which is to be used in the treatment. At step 11, the dose is monitored, and at step 12, the output end 62 of the waveguide 60 is located in position. At step 13, the treatment takes place by moving the wheel 12 so that the element 20 is moved out of alignment and one of the elements 14,16 or 18 is moved into alignment depending on the treatment wavelength which has been selected.

At step 14, the treatment is controlled by countdown of the timer 104. During the course of treatment, the filter wheels 12 and 24 can be selectively controlled to go back to application of UV light and the spectrum analyser used to determine if any fluorescence is detected from the treatment area. If no fluorescence is detected before the timer 104 runs down, the lamp 10 can be shut off my rotating the wheel 12 to bring the element 20 into alignment with the wheel, as the lack of fluorescence is indicative of the fact that treatment has been completed and the unwanted cells destroyed, thereby indicating that it is not necessary to continue for the full time previously set by the timer 104.

At step 15, the data following the treatment is logged into the database 52, including the time of actual treatment, the nature of any fluorescence still existing after treatment, and also a photograph of the treatment area captured by the camera 70.

Since modifications within the spirit and scope of the invention may readily be effected by persons skilled within the art, it is to be understood that this invention is not limited to the particular embodiment described by way of example hereinabove.



SCHEMATIC LAYOUT OF MEDICAL POLI LIGHT SYSTEM.

Fig 1

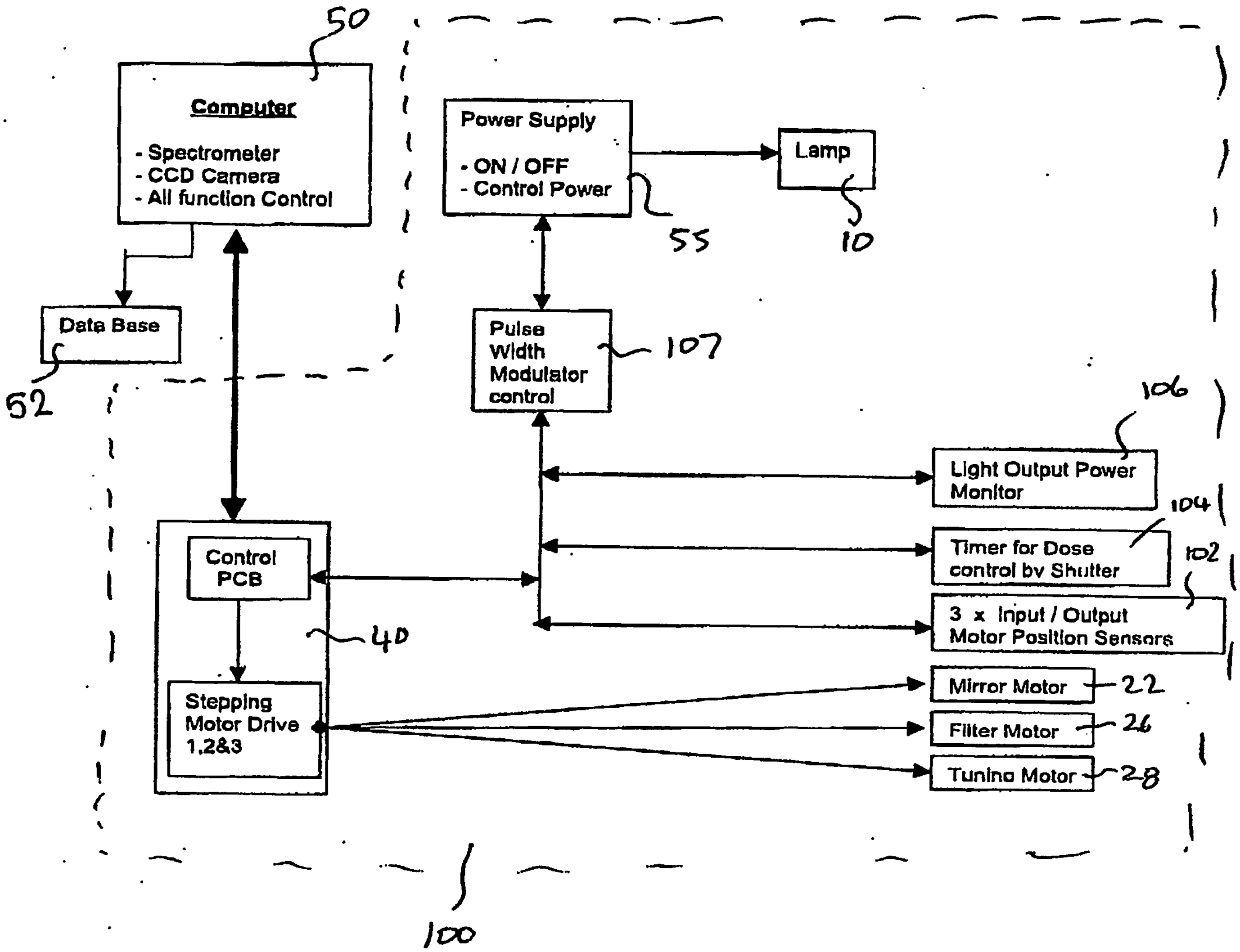

50
Computer
- Spectrometer
- CCD Camera
- All function Control
Data Base
52
Power Supply
- ON / OFF
- Control Power
55
Lamp
10
Pulse Width Modulator control
107
106
Light Output Power Monitor
104
Timer for Dose control by Shutter
102
3 x Input / Output Motor Position Sensors
Control PCB
40
Stepping Motor Drive 1,2&3
Mirror Motor
22
Filter Motor
26
Tuning Motor
28
100

Fig 2

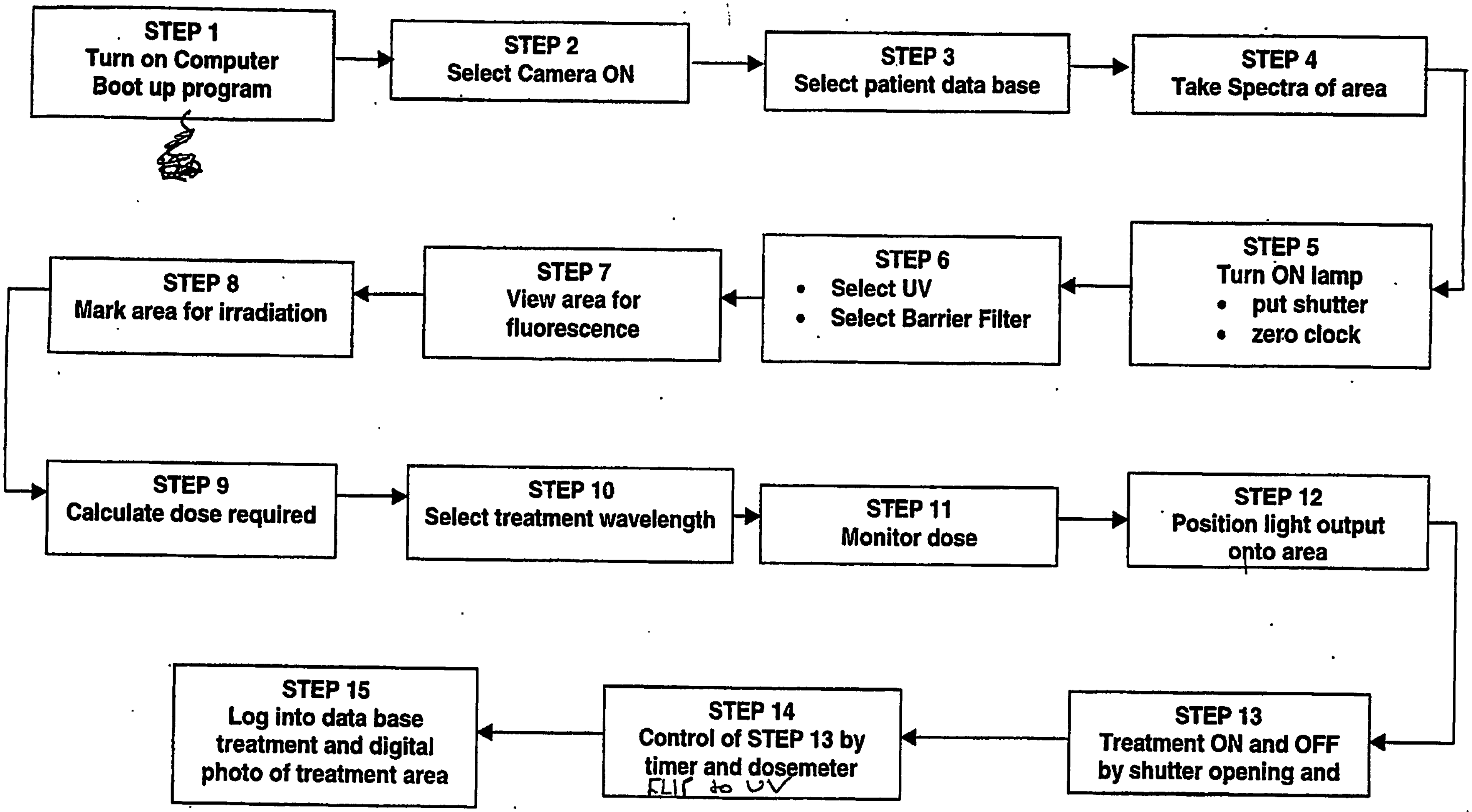

STEP 1
Turn on Computer
Boot up program
STEP 2
Select Camera ON
STEP 3
Select patient data base
STEP 4
Take Spectra of area
STEP 5
Turn ON lamp
• put shutter
• zero clock
STEP 6
• Select UV
• Select Barrier Filter
STEP 7
View area for fluorescence
STEP 8
Mark area for irradiation
STEP 9
Calculate dose required
STEP 10
Select treatment wavelength
STEP 11
Monitor dose
STEP 12
Position light output onto area
STEP 13
Treatment ON and OFF by shutter opening and
STEP 14
Control of STEP 13 by timer and dosemeter
FLIP to UV
STEP 15
Log into data base treatment and digital photo of treatment area

Fig 3